



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[EPA-HQ-OW-2015-0174; FRL-7253.1-02-OW]

RIN 2040-AG21

Restoring Protective Human Health Criteria in Washington

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On April 1, 2022, the Environmental Protection Agency (EPA) determined that Washington's human health criteria (HHC) for certain pollutants were not protective of Washington's designated uses and were not based on sound scientific rationale and, accordingly, proposed to restore protective HHC for those pollutants in Washington's waters. EPA is finalizing protective and science-based Federal HHC in this final rule to protect Washington's waters, including waters where tribes hold treaty-reserved rights to fish.

DATES: This final rule is effective on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2015-0174. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <https://www.regulations.gov>.

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I. General Information

A. Does this Action Apply to Me?

Entities that are subject to Clean Water Act (CWA) regulatory programs such as industrial facilities, stormwater management districts, or publicly owned treatment works (POTWs) that discharge pollutants to surface waters of the United States under the State of Washington's jurisdiction could be affected by this rulemaking because the Federal water quality standards (WQS) promulgated by EPA are applicable WQS for surface waters in Washington for

CWA purposes. Categories and entities that could potentially be affected by this rulemaking include the following:

Category	Examples of potentially affected entities
Industry	Industrial point sources discharging pollutants to waters of the United States in Washington.
Municipalities	Publicly owned treatment works or similar facilities discharging pollutants to waters of the United States in Washington.
Stormwater Management Districts	Entities responsible for managing stormwater in the State of Washington.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities that could be indirectly affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. How did EPA Develop this Final Rule?

In developing this final rule, EPA carefully considered the public comments and feedback received from interested parties. EPA provided a 60-day public comment period after publishing the proposed rulemaking in the *Federal Register* on April 1, 2022.¹ In addition, EPA held two online public hearings on May 24 and 25, 2022, to discuss the contents of the proposed rulemaking and accept verbal public comments.

Over 20 organizations and individuals submitted comments on a range of issues. EPA also received over 300 letters from individuals associated with a mass letter writing campaign. Some comments addressed issues beyond the scope of the rulemaking, and thus EPA did not consider them in finalizing this rule. In this preamble, EPA provides summaries of certain comments received on aspects of the proposal that generated the most commenter interest. For a complete summary of all comments received and EPA's responses, see EPA's Response to Comments document in the official public docket.

¹ See *Restoring Protective Human Health Criteria in Washington: Proposed Rule*, 87 FR 19046, April 1, 2022.

II. Background

A. Statutory and Regulatory Background

CWA section 101(a)(2) establishes as a national goal “water quality which provides for the protection and propagation of fish, shellfish, and wildlife, and recreation in and on the water, wherever attainable.” EPA interprets these CWA section 101(a)(2) goals to include, at a minimum, designated uses providing for the protection of aquatic communities and human health related to consumption of fish and shellfish.²

Consistent with the CWA, EPA’s WQS program assigns to states and authorized tribes the primary authority for adopting WQS.³ CWA section 303(c)(2)(A) and EPA’s implementing regulations at 40 CFR part 131 require, among other things, that a state’s WQS specify appropriate designated uses of the waters, and water quality criteria that protect those uses. EPA’s regulations at 40 CFR 131.11(a)(1) provide that “[s]uch criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use. For waters with multiple use designations, the criteria shall support the most sensitive designated use.”

Under CWA section 304(a), EPA periodically publishes criteria (including HHC) recommendations for states to consider when adopting water quality criteria for particular pollutants to protect CWA section 101(a) goal uses. Where EPA has published recommended criteria, states should establish numeric water quality criteria based on EPA’s CWA section 304(a) criteria recommendations, CWA section 304(a) criteria recommendations modified to reflect site-specific conditions, or other scientifically defensible methods (40 CFR 131.11(b)(1)).

After a state adopts a new or revised WQS, the state must submit it to EPA for review and action in accordance with CWA section 303(c).⁴ If EPA determines that a state’s new or

² USEPA. 2000. Memorandum 1BWQSP-00-03. U.S. Environmental Protection Agency, Office of Water, Washington, DC, <https://www.epa.gov/sites/production/files/2015-01/documents/standards-shellfish.pdf>.

³ 33 U.S.C. 1313(a), (c).

⁴ 33 U.S.C. 1313(c)(2)(A), (c)(3).

revised WQS is not consistent with the requirements of the Act, the state has 90 days to submit a modified standard. If the state fails to adopt a revised WQS that EPA approves, CWA section 303(c)(4)(A) requires EPA to propose and promulgate a revised or new standard for the waters involved. In addition, CWA section 303(c)(4)(B) grants the EPA Administrator discretion to determine “that a revised or new standard is necessary to meet the requirements of [the Act].”⁵ After making such a determination, known as an Administrator’s Determination,⁶ the agency must “promptly” propose an appropriate WQS and finalize it within ninety days unless the state adopts an acceptable standard in the interim.⁷

B. EPA’s General Approach for Deriving Human Health Criteria

EPA’s 2000 *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*⁸ (2000 Methodology) describes the methods EPA uses when developing national CWA section 304(a) recommended HHC and when promulgating Federal HHC. The 2000 Methodology also serves as guidance to states and authorized tribes for developing their own HHC. EPA’s guidance informs, but does not dictate, EPA’s implementation of the applicable statutory and regulatory requirements noted above. EPA’s 2000 Methodology recommends that HHC be designed to reduce the risk of adverse cancer and non-cancer effects occurring from lifetime exposure to pollutants through the ingestion of drinking water and consumption of fish/shellfish obtained from inland and nearshore waters. Consistent with the 2000 Methodology, EPA’s practice is to establish a criterion for both drinking water ingestion and consumption of fish/shellfish from inland and nearshore waters combined and a separate criterion based on ingestion of fish/shellfish from inland and nearshore waters alone. This latter criterion applies in cases where the designated uses of a waterbody include supporting

⁵ *Id.* at (c)(4)(B).

⁶ 40 CFR 131.22(b)

⁷ 33 U.S.C. 1313(c)(4)(B).

⁸ USEPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. <https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf>.

fish/shellfish for human consumption but not drinking water supply sources (e.g., non-potable estuarine waters).

Consistent with EPA's 2000 Methodology, EPA establishes HHC based on two types of toxicological endpoints: (1) carcinogenicity; and (2) noncancer toxicity (i.e., all adverse effects other than cancer). Where sufficient data are available, EPA derives criteria using both carcinogenic and non-carcinogenic toxicity endpoints and uses the lower (i.e., more health-protective) value. EPA calculates HHC for carcinogenic effects using the following input parameters: cancer slope factor (CSF), cancer risk level (CRL), body weight, drinking water intake rate, fish consumption rate (FCR), and a bioaccumulation factor(s). EPA calculates HHC for both non-cancer and nonlinear carcinogenic effects using a reference dose (RfD) and relative source contribution (RSC) in place of a CSF and CRL (the remaining inputs are the same for both toxicology endpoints). The RSC is applied to apportion the RfD among the media and exposure routes of concern for a particular chemical to ensure that an individual's total exposure from all exposure sources does not exceed the RfD. Each of these inputs is discussed in more detail in sections II.B.a through II.B.d of this preamble and in EPA's 2000 Methodology.⁹

a. Cancer Risk Level

Consistent with the 2000 Methodology, EPA generally assumes, in the absence of data to indicate otherwise, that carcinogens exhibit linear "non-threshold" dose-responses which means that there are no "safe" or "no-effect" levels. Therefore, EPA calculates HHC for carcinogenic effects as pollutant concentrations corresponding to lifetime increases in the risk of developing cancer. EPA calculates HHC values at a 10^{-6} (one in one million) CRL and recommends that states and authorized tribes use CRLs of 10^{-6} or 10^{-5} (one in one hundred thousand) when

⁹ *Id.*

deriving HHC for the general population.¹⁰ EPA notes that states and authorized tribes can also choose a more health protective risk level, such as 10^{-7} (one in ten million), when deriving HHC.

b. Cancer Slope Factor and Reference Dose

A dose-response assessment is required to understand the quantitative relationships between exposure to a pollutant and adverse health effects. EPA evaluates dose-response relationships based on the available data from animal toxicity and human epidemiological studies to derive dose-response metrics. For carcinogenic effects, EPA uses an oral CSF to derive the HHC. The oral CSF is an upper bound, approximating a 95 percent confidence limit, on the increased cancer risk from a lifetime oral exposure to a pollutant. For non-carcinogenic effects, EPA uses the reference dose (RfD) to calculate the HHC. A RfD is an estimate of a daily oral exposure of an individual to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. A RfD is often derived from a laboratory animal toxicity multi-dose study from which a no-observed-adverse-effect level (NOAEL), lowest-observed-adverse-effect level (LOAEL), or benchmark dose level can be identified. However, human epidemiology studies can also be used to derive a RfD. Uncertainty factors are applied to account for gaps or deficiencies in the available data (e.g., differences in response among humans) for a chemical. For the majority of EPA's latest (2015) updated national CWA section 304(a) recommended HHC, EPA's Integrated Risk Information System (IRIS)¹¹ was the source of both cancer and noncancer toxicity values (i.e., RfD and CSF).¹² For some pollutants, EPA selected risk assessments produced by other EPA program offices (e.g., Office of Pesticide Programs,

¹⁰ EPA's 2000 Methodology also states: "Criteria based on a 10^{-5} risk level are acceptable for the general population as long as states and authorized tribes ensure that the risk to more highly exposed subgroups (sport fishers or subsistence fishers) does not exceed the 10^{-4} level."

¹¹ USEPA. Integrated Risk Information System (IRIS). U.S. Environmental Protection Agency, Office of Research and Development, Washington, DC www.epa.gov/iris.

¹² Final Updated Ambient Water Quality Criteria for the Protection of Human Health (80 FR 36986, June 29, 2015). See also: USEPA. 2015. Final 2015 Updated National Recommended Human Health Criteria. U.S. Environmental Protection Agency, Office of Water, Washington, DC, <https://www.epa.gov/wqc/human-health-water-quality-criteria>.

Office of Water, Office of Land and Emergency Management), other national and international programs, and state programs.

c. Exposure Assumptions

EPA's exposure assumptions provide an overall level of protection targeted at the high end of the general population, as stated in the 2000 Methodology. EPA selects a combination of high-end and central tendency inputs to the criteria derivation equation and avoids "double counting" of exposures and combining unlikely co-occurrences. Consistent with the 2015 national CWA section 304(a) recommended HHC, EPA uses a default drinking water intake rate of 2.4 liters per day (L/day) and default rate of 22 grams per day (g/day) for consumption of fish and shellfish from inland and nearshore waters, multiplied by pollutant-specific bioaccumulation factors (BAFs) to account for the amount of the pollutant in the edible portions of the ingested species.

EPA's national default drinking water intake rate of 2.4 L/day represents the per capita estimate of combined direct and indirect community water ingestion at the 90th percentile for adults ages 21 and older.¹³ EPA's national FCR of 22 g/day represents the 90th percentile consumption rate of fish and shellfish from inland and nearshore waters for the U.S. adult population 21 years of age and older, based on National Health and Nutrient Examination Survey (NHANES) data from 2003 to 2010.^{14,15} EPA calculates HHC using a default body weight of 80 kilograms (kg), the average weight of a U.S. adult age 21 and older, based on NHANES data from 1999 to 2006.

¹³ USEPA. 2011. EPA Exposure Factors Handbook. 2011 edition (EPA 600/R-090/052F). <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252>.

¹⁴ USEPA. 2014. Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010). United States Environmental Protection Agency, Washington, DC, EPA 820-R-14-002.

¹⁵ EPA's national FCR is based on the total rate of consumption of fish and shellfish from inland and nearshore waters (including fish and shellfish from local, commercial, aquaculture, interstate, and international sources). This is consistent with a principle that each state does its share to protect people who consume fish and shellfish that originate from multiple jurisdictions.

Prior to publication of the 2000 Methodology, in which EPA began recommending the use of BAFs to reflect the uptake of a contaminant from all sources by fish and shellfish,¹⁶ EPA relied on bioconcentration factors (BCFs) to estimate chemical accumulation of waterborne chemicals by aquatic organisms. However, BCFs only account for chemical accumulation in aquatic organisms through exposure to chemicals in the water column. In 2000, EPA noted that “there has been a growing body of scientific knowledge that clearly supports the observation that bioaccumulation and biomagnification occur and are important exposure issues to consider for many highly hydrophobic organic compounds and certain organometallics.” For that reason, the 2000 Methodology observed that “[f]or highly persistent and bioaccumulative chemicals that are not easily metabolized, BCFs do not reflect what the science indicates.”¹⁷ Therefore, consistent with the 2000 Methodology EPA uses, when data are available, measured or estimated BAFs, which account for chemical accumulation in aquatic organisms from all potential exposure routes, including, but not limited to, food, sediment, and water.¹⁸ EPA uses separate BAFs for each trophic level to account for potential biomagnification of chemicals in aquatic food webs, as well as physiological differences among organisms that may affect bioaccumulation.¹⁹

EPA derives national default BAFs, in part, as a resource for states and authorized tribes with limited resources for deriving site-specific BAFs.²⁰ EPA’s approach for developing national BAFs represents the long-term average bioaccumulation potential of a pollutant in aquatic

¹⁶ USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. <https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf> at 5-4. (Explaining that “[t]he 1980 Methodology for deriving 304(a) criteria for the protection of human health emphasized the assessment of bioconcentration (uptake from water only) through the use of the BCF... The 2000 Human Health Methodology revisions contained in this chapter emphasize the measurement of bioaccumulation (uptake from water, sediment, and diet) through the use of the BAF.”).

¹⁷ 65 FR 66444 (November 3, 2000).

¹⁸ USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. <https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf>.

¹⁹ USEPA. 2003. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). Technical Support Document Volume 2: Development of National Bioaccumulation Factors. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-03-030. <https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf>.

²⁰ 65 FR 66444 (November 3, 2000).

organisms that are commonly consumed by humans across the United States. In the 2015 national CWA section 304(a) recommended HHC update, EPA relied on field-measured BAFs and laboratory-measured BCFs available from peer-reviewed, publicly available databases to develop national BAFs for three trophic levels of fish.²¹ If this information was not available, EPA selected octanol-water partition coefficients (K_{ow} values) from publicly available, published peer-reviewed sources for use in calculating national BAFs. As an additional line of evidence, EPA reported model-estimated BAFs for every chemical based on the Estimation Program Interface (EPI) Suite to support the field-measured or predicted BAFs.²²

Although EPA uses national default exposure-related input values to calculate national CWA section 304(a) recommended criteria, EPA's methodology notes a preference for the use of local data, when available, to calculate HHC (e.g., locally derived FCRs, drinking water intake rates and body weights, and waterbody-specific bioaccumulation rates) over national default values. Using local data helps ensure that HHC represent local conditions.²³ EPA also recommends, where sufficient data are available, selecting an FCR that reflects consumption that is not suppressed by fish availability or concerns about the safety of available fish.²⁴ Deriving criteria using an unsuppressed FCR furthers the restoration goals of the CWA and ensures protection of human health as pollutant levels decrease, fish habitats are restored, and fish

²¹ Final Updated Ambient Water Quality Criteria for the Protection of Human Health (80 FR 36986, June 29, 2015). See also: USEPA. 2015. Final 2015 Updated National Recommended Human Health Criteria. U.S. Environmental Protection Agency, Office of Water, Washington, DC, <https://www.epa.gov/wqc/human-health-water-quality-criteria>.

²² *Id.*

²³ USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. <https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf>.

²⁴ As noted by the National Environmental Justice Advisory Council in the 2002 publication *Fish Consumption and Environmental Justice*, "a suppression effect may arise when fish upon which humans rely are no longer available in historical quantities (and kinds), such that humans are unable to catch and consume as much fish as they had or would. Such depleted fisheries may result from a variety of affronts, including an aquatic environment that is contaminated, altered (due, among other things, to the presence of dams), overdrawn, and/or overfished. Were the fish not depleted, these people would consume fish at more robust baseline levels. . . . In the Pacific Northwest, for example, compromised aquatic ecosystems mean that fish are no longer available for tribal members to take, as they are entitled to do in exercise of their treaty rights."). National Environmental Justice Advisory Council, *Fish Consumption and Environmental Justice*, p.44, 46 (2002) (NEJAC Fish Consumption Report), available at https://www.epa.gov/sites/default/files/2015-02/documents/fish-consump-report_1102.pdf.

availability increases. Moreover, as explained further below, selecting an FCR that reflects unsuppressed fish consumption could be necessary where tribal treaty or other reserved fishing rights apply. In such circumstances, if sufficient data regarding unsuppressed fish consumption levels are unavailable or inconclusive, states should consult with tribes when deciding which fish consumption data should be used in selecting an FCR.

d. Relative Source Contribution

The inclusion of an RSC factor²⁵ is important for protecting public health. When deriving HHC for non-carcinogens and nonlinear carcinogens, EPA includes an RSC factor to account for sources of exposure other than drinking water and consumption of fish and shellfish from inland and nearshore waters. These other sources of exposure include but are not limited to ocean fish consumption (which is not included in EPA's default national FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and inhalation exposure. Using an RSC ensures that the level of a chemical allowed by a water quality criterion, when combined with other exposure sources, will not result in exposures that exceed the RfD, thus helping to prevent adverse health effects from aggregate exposure to a given chemical over a person's lifetime. EPA's guidance²⁶ includes an approach for determining an appropriate RSC for a given pollutant ranging in value from 0.2 to 0.8 to ensure that drinking water and fish consumption alone are not apportioned the entirety of the RfD. This approach, known as the Exposure Decision Tree, considers the adequacy of available exposure data, levels of exposure, relevant sources/media of exposure, and regulatory agendas. As explained below in section III.B.d of this preamble, EPA made science-based adjustments to the application of the RSC in this rulemaking to avoid "double counting" exposures.

C. Prior EPA Actions Related to Washington's Human Health Criteria

²⁵ "[RSC] defines the portion of the total exposure that comes from ingestion of water and fish from the ambient water body of interest. Other exposure information such as that from dietary, inhalation, and dermal routes should be considered and accounted for as part of the RSC human exposure analysis." <https://www.epa.gov/wqs-tech/supplemental-module-human-health-ambient-water-quality-criteria>.

²⁶ *Id.*

In 1992, EPA promulgated the National Toxics Rule (NTR) at 40 CFR 131.36, establishing chemical-specific numeric criteria for 85 priority toxic pollutants for 14 states and territories (states), including Washington, that were not in compliance with the requirements of CWA section 303(c)(2)(B). Subsequently, when states covered by the NTR adopted their own criteria for toxic pollutants that were consistent with the CWA and EPA's implementing regulations, EPA amended the NTR to remove those chemical-specific criteria for those states. In 2015, Washington was one of the states that remained covered by the NTR.

On September 14, 2015, the EPA Administrator determined that updated HHC for Washington were "necessary" pursuant to CWA section 303(c)(4)(B). EPA proposed HHC to protect the health of Washington residents, including tribes with treaty-reserved rights to fish.²⁷ In that proposal, EPA explained that the majority of waters under Washington's jurisdiction are subject to tribal treaty-reserved fishing rights.²⁸ To give effect to such rights in establishing revised WQS for Washington waters, EPA determined that tribal treaty fishing rights "appropriately must be considered when determining which criteria are necessary to adequately protect Washington's fish and shellfish harvesting designated uses."²⁹ Specifically, EPA proposed to consider the tribal populations exercising their legal right to harvest and consume fish and shellfish as the general population for purposes of deriving protective HHC. To this end, EPA proposed HHC based on an FCR of 175 g/day and CRL of 10^{-6} to reflect consideration of tribal treaty-reserved rights, as informed by consultation with the tribes and fish consumption surveys of tribal members.³⁰ In addition to an FCR and CRL calculated to ensure protection of applicable tribal treaty-reserved rights, EPA also utilized other inputs to derive the proposed HHC based on the agency's latest scientific knowledge. Specifically, EPA calculated the

²⁷ 80 FR 55063 (September 14, 2015).

²⁸ *Id.* at 55067.

²⁹ *Id.*

³⁰ *Id.* at 55067-68.

proposed HHC using the national trophic level four BAFs and updated chemical-specific RSC values from its June 2015 CWA section 304(a) recommended criteria updates.³¹

Before EPA finalized the proposed Federal criteria, the State of Washington adopted HHC following an extensive public process and submitted the updated HHC to EPA for review on August 1, 2016. The updated HHC incorporated some of the new data and information from EPA's June 2015 CWA section 304(a) criteria updates. Washington's HHC were based on the same 175 g/day FCR and 10^{-6} CRL that EPA used to derive the proposed Federal HHC, with the exception of the CRL for polychlorinated biphenyls (PCBs).³² Although Washington used the same FCR and CRL as EPA, Washington used BCFs instead of BAFs and used an RSC of 1. The scientific inputs of BCFs and an RSC of 1 do not reflect the latest scientific knowledge.

On November 15, 2016, EPA partially approved and partially disapproved Washington's HHC.³³ For the criteria that were disapproved, EPA concurrently signed a final rule promulgating the Federal criteria it had proposed in 2015.³⁴ Like EPA's 2015 proposal, the 2016 final rule articulated EPA's conclusion that it is necessary and appropriate to consider tribal treaty-reserved rights within the framework of the CWA and provided a discussion of the tribal treaties relevant to the State of Washington and applicable case law.³⁵ The 2016 final rule was informed by public comment that addressed both the proposed criteria and EPA's consideration of tribal treaties, as well as consultation with a number of federally recognized tribes.

EPA's disapproval of Washington's HHC in 2016 was largely predicated on Washington's use of input values that were not reflective of sound scientific rationale. In its letter to the State, EPA explained that the agency "evaluated Washington's criteria values against criteria that EPA determined would be protective of the State's designated uses and scientifically

³¹ *Id.* at 55068-69.

³² For PCBs, Washington's criteria were based on a chemical-specific CRL of 2.3×10^{-5} .

³³ Letter from Dan D. Opalski, Director, EPA Region 10 Office of Water and Watersheds to Maia Bellon, Director, Department of Ecology, Re: EPA's Partial Approval/Partial Disapproval of Washington's Human Health Water Quality Criteria and Implementation Tools; Enclosure, Technical Support Document (November 15, 2016) (2016 Partial Approval/Partial Disapproval).

³⁴ 81 FR 85417 (November 28, 2016).

³⁵ 81 FR 85422-27 (November 28, 2016).

defensible (e.g., based on appropriate bioaccumulation factors (BAFs) and protective relative source contribution (RSC) values of less than 1).”³⁶ EPA found that Washington had not demonstrated that the majority of its criteria were based on sound scientific rationale as required by the CWA and EPA’s implementing regulations.³⁷ Specifically for PCBs, EPA found that Washington had not provided adequate support or analysis to justify its use of a chemical-specific CRL (2.3×10^{-5}) that was less stringent than the CRL used for all other pollutants, and did not explain how the use of this CRL was protective of the State’s designated uses.³⁸

With respect to the criteria that EPA approved, the agency also explained that “while the EPA carefully considers the scientific defensibility and protectiveness of both the inputs used to derive criteria and the resulting criteria values, it is ultimately on the criteria values that the EPA takes approval or disapproval action under CWA section 303(c).”³⁹ After evaluating Washington’s criteria against criteria using appropriate scientific inputs, EPA determined that certain of Washington’s criteria were as or more stringent than scientifically defensible criteria that the EPA determined would be protective of Washington’s designated uses.⁴⁰ Accordingly, EPA approved those criteria.⁴¹

In a petition dated February 21, 2017, several regulated entities requested that EPA reconsider its November 15, 2016, partial disapproval and repeal its concurrent promulgated Federal criteria.⁴² Following the 2017 petition, Washington and several federally recognized

³⁶ 2016 Partial Approval/Disapproval at 3.

³⁷ *Id.* at 16-17.

³⁸ *Id.* at 26 (Determining that Washington “did not provide adequate justification for using the Washington Department of Health cancer risk level for this specific chemical and then adjusting that cancer risk level so that the criteria would be equivalent to the NTR criteria” and “did not demonstrate how the criteria were derived using a cancer risk level that is based on scientifically sound rationale and protective of applicable designated uses, including the tribal subsistence fishing portion of the fish and shellfish harvesting use as informed by treaty-reserved fishing rights.”).

³⁹ *Id.* at 8.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² Petition submitted by Northwest Pulp and Paper Association, America Forest and Paper Association, Association of Washington Business, Greater Spokane Incorporated, Treated Wood Council, Western Wood Preservers Institute, Utility Water Act Group and the Washington Farm Bureau.

tribes with treaty-reserved fishing rights sent letters urging EPA to deny the petition and to leave the federally promulgated HHC in place.⁴³

Despite objections from the State and several tribes, on May 10, 2019, EPA granted the 2017 industry petition by reversing the agency's prior partial disapproval to an approval of certain HHC ('2019 Reconsidered HHC') and subsequently issuing a final rule withdrawing the federally promulgated criteria.⁴⁴ EPA's May 10, 2019 approval concluded that the State's reliance on scientific inputs that were not reflective of the latest science was an appropriate risk-management decision.⁴⁵ The withdrawal of the Federal criteria went into effect on June 12, 2020, and as of that date, the HHC submitted by Washington on August 1, 2016 and approved by EPA on May 10, 2019 were in effect for CWA purposes.

On June 6, 2019, the State of Washington filed a complaint challenging the legality of EPA's May 2019 decision to reverse its November 2016 partial disapproval.⁴⁶ The Sauk-Suiattle Indian Tribe and Quinault Indian Nation subsequently joined Washington's lawsuit as plaintiff-intervenors. On June 6, 2020, following EPA's withdrawal of the promulgated Federal HHC, another lawsuit was filed by the Makah Indian Tribe, the Pacific Coast Federation of Fishermen's Associations, and environmental groups challenging both EPA's withdrawal of the federally promulgated HHC and its May 10, 2019 decision to reverse the November 2016 partial disapproval.⁴⁷ In September 2020, the Plaintiffs in the case filed by the State of Washington amended their complaints to also challenge EPA's rule withdrawing the Federal HHC.

⁴³ EPA received letters from the Washington State Department of Ecology, Washington State Attorney General, the Northwest Indian Fisheries Commission, the Lower Elwha Klallam Tribe, the Nooksack Indian Tribe, the Jamestown S'Klallam Tribe, and Earthjustice (on behalf of the Pacific Coast Federation of Fishermen's Associations, Institute for Fisheries Resources, and several Washington Waterkeepers).

⁴⁴ May 10, 2019 letter and enclosed Technical Support Document from Chris Hladick, Regional Administrator, EPA Region 10, to Maia Bellon, Director, Department of Ecology, Re: EPA's Reversal of the November 15, 2016 Clean Water Act section 303(c) Partial Disapproval of Washington's Human Health Water Quality Criteria and Decision to Approve Washington's Criteria; Withdrawal of Certain Federal Water Quality Criteria Applicable to Washington, 85 FR 28494 (May 13, 2020).

⁴⁵ May 10, 2019 letter at pp. 8, 14-15.

⁴⁶ *State of Washington v. U.S. Env't'l Prot. Agency*, No. 2:19-cv-884-RAJ (W.D. Wash.).

⁴⁷ *Puget Soundkeeper Alliance et al. v. U.S. Env't'l Prot. Agency*, No. 2:20-cv-907-RAJ (W.D. Wash.).

Consistent with Executive Order 13990,⁴⁸ in February 2021, EPA sought and was granted an abeyance in both cases to conduct an initial review to determine whether it intended to reconsider the challenged actions. During this initial three-month abeyance, EPA decided to reconsider the challenged actions. Based on its initial review of the agency's prior actions, EPA sought a longer abeyance from the court, expressing substantial concern that Washington's HHC may not be adequately protective and may not be based on sound scientific rationale. On July 6, 2021, the Court granted EPA an abeyance to reconsider its prior actions and to propose protective HHC for Washington and take final action on the proposal within 18 months. EPA proposed protective HHC for Washington on April 1, 2022,⁴⁹ and is now finalizing protective HHC for Washington in this final rule.

III. Derivation of Human Health Criteria for Washington

A. Scope of EPA's Final Rule

After consideration of all comments received on EPA's proposed rulemaking, EPA is finalizing Federal criteria that supersede the 2019 Reconsidered HHC for CWA purposes.⁵⁰ EPA's final rule does not change or supersede the Federal HHC that EPA promulgated for arsenic,⁵¹ methylmercury, or bis (2-chloro-1-methylethyl) ether in 2016 and that remain in place for CWA purposes, nor Washington's HHC that EPA approved in 2016 and have remained in effect since that time. EPA's final rule also does not change or supersede Washington's HHC for dioxin and thallium that EPA approved in 2019. EPA had previously taken no action on these two pollutants in 2016.

Some commenters asked EPA to quickly take separate prompt action to strengthen dioxin criteria and establish criteria for per- and polyfluoroalkyl substances (PFAS) unless Washington addresses those pollutants itself in a future State rulemaking. As noted in EPA's Response to

⁴⁸ 86 FR 7037 (January 25, 2021).

⁴⁹ See *Restoring Protective Human Health Criteria in Washington: Proposed Rule*, 87 FR 19046, April 1, 2022.

⁵⁰ See 40 CFR 131.21(c).

⁵¹ EPA promulgated arsenic HHC for Washington in the National Toxics Rule of 1992. EPA's Federal rule in 2016 moved the arsenic criteria from 40 CFR 131.36 to 40 CFR 131.45.

Comment document in the docket for this rule, such comments are beyond the scope of this rulemaking.

Finally, certain commenters referred to EPA's prior actions related to HHC for arsenic and mercury in Washington. EPA's proposed rulemaking did not address those prior actions, which were based on the administrative record before the agency at that time, nor did EPA solicit comment on those actions. Therefore, such comments are also beyond the scope of this rule.

The HHC in this final rule apply to surface waters under the State of Washington's jurisdiction, and not to waters within Indian country,⁵² unless otherwise specified in Federal law.

B. Washington-Specific Human Health Criteria Inputs

a. Fish Consumption Rate, Body Weight, Drinking Water Intake

EPA is finalizing HHC for Washington using the same FCR of 175 g/day, body weight of 80 kg and drinking water intake rate of 2.4 L/day that the agency proposed in its April 1, 2022, proposed rulemaking,⁵³ which are the same values Washington used in 2016⁵⁴ and that EPA used in its 2016 Federal rule.⁵⁵ The comments addressing these input values are briefly summarized below.

With respect to the FCR, some commenters asserted that protective HHC should accurately account for the amount of fish people are eating, and that EPA was right to propose HHC using an FCR of 175 g/day. However, the same commenters state that 175 g/day is a compromise rate and is therefore, not conservative because many communities in Washington eat more than 175 g/day, even with suppressed fish stocks. Those commenters assert that 175 g/day is only acceptable if that rate is paired with a CRL of one in one million (10^{-6}) and the most recent science for the other inputs.

⁵² See 18 U.S.C. 1151 for definition of Indian Country.

⁵³ See *Restoring Protective Human Health Criteria in Washington: Proposed Rule*, 87 FR 19046, April 1, 2022.

⁵⁴ Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment*. August 2016. Ecology Publication no. 16-10-025.

⁵⁵ *Revision of Certain Water Quality Standards Applicable to Washington*, 81 FR 85417 (November 28, 2016).

Other commenters asserted that 175 g/day is an inappropriate FCR to use to derive HHC in Washington, and/or that it should not be paired with a 10^{-6} CRL. These commenters state that lower FCRs, or greater CRLs of one in one hundred thousand (10^{-5}) or one in ten thousand (10^{-4}), would be protective of all consumers in Washington, including tribes. Some commenters characterized 175 g/day as a high-biased estimate of fish consumption that is based on an outdated survey method. Additionally, commenters assert that 175 g/day is too high to use to derive HHC for Washington because it includes consumption of fish that predominantly accumulate pollutants in waters outside of Washington's jurisdiction (i.e., the open ocean). Commenters state that EPA relies in part on an argument that fish consumption in Washington is suppressed but assert that EPA has not provided scientific evidence of such suppression or guidance on how to account for suppression. These commenters state that there is no evidence of lower fish stocks limiting consumption, and that fish availability should not be a factor in setting HHC since those criteria do not impact fish availability.

EPA reiterates its explanation in the proposed rulemaking that it does not have new data or information suggesting a need to revisit the inputs utilized in the 2016 rule.⁵⁶ Thus, EPA is applying the same rationale here as the agency articulated to support its use of those inputs in the 2016 Federal rule. The agency has concluded that it is important to keep these values consistent between the HHC in this rule and the other HHC that this rule will not impact (i.e., the HHC that Washington adopted and EPA approved in 2016, and the Federal HHC that remain in place for arsenic, methylmercury, or bis (2-chloro-1-methylethyl) ether), because these values are associated with the population that the criteria are intended to protect and are not pollutant-specific. For detailed responses to all comments received, see EPA's Response to Comment document in the docket for this rule.

b. Pollutant-Specific Reference Doses and Cancer Slope Factors

⁵⁶ *Id.* at 85420; 85426-428.

EPA is finalizing HHC for Washington using the same reference doses and cancer slope factors that the agency proposed in its April 1, 2022, proposed rulemaking,⁵⁷ which are the same values Washington used in 2016⁵⁸ and that EPA used in its 2016 Federal rule.⁵⁹ These are the same toxicity values that EPA uses in its national CWA section 304(a) recommended HHC. While there may be new toxicity information available for certain pollutants that is not yet reflected in EPA's CWA section 304(a) national recommended HHC, such information has not yet been reviewed through EPA's comprehensive CWA section 304(a) criteria development process and therefore is not incorporated into this final rule.⁶⁰ See Table 1, columns B1 and B3 of this preamble for a list of EPA's toxicity factors by pollutant.

EPA only received comments on reference doses and cancer slope factors in the context of specific pollutants, namely PCBs and mercury. As noted above, comments on mercury are beyond the scope of this rulemaking. For comments on PCBs, see below and EPA's Response to Comment document in the docket for this rule.

c. Cancer Risk Level

EPA is finalizing HHC for Washington using the same CRL of 10^{-6} that the agency proposed in its April 1, 2022, proposed rulemaking for all pollutants, including PCBs.⁶¹ This is the same CRL Washington used in 2016 for all pollutants except for PCBs⁶² and that EPA used in its 2016 Federal rule for all pollutants.⁶³

⁵⁷ See *Restoring Protective Human Health Criteria in Washington: Proposed Rule*, 87 FR 19046, April 1, 2022.

⁵⁸ Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment*. August 2016. Ecology Publication no. 16-10-025.

⁵⁹ *Revision of Certain Water Quality Standards Applicable to Washington*, 81 FR 85417 (November 28, 2016).

⁶⁰ For example, there are 7 polycyclic aromatic hydrocarbons for which there is new toxicity information available since the promulgation of the 2016 Federal rule. Because the CWA section 304(a) criteria development process can take several years, EPA is not able to review this information and complete this rulemaking by the end of the 18-month abeyance. Once EPA has developed updated CWA section 304(a) criteria for these pollutants, the State may evaluate its HHC for these pollutants (e.g., during a triennial review), adopt new HHC based on the CWA section 304(a) updates, and submit these HHC to EPA for review.

⁶¹ See *Restoring Protective Human Health Criteria in Washington: Proposed Rule*, 87 FR 19046, April 1, 2022.

⁶² Department of Ecology. *Washington State Water Quality Standards: Human health criteria and implementation tools, Overview of key decisions in rule amendment*. August 2016. Ecology Publication no. 16-10-025.

⁶³ *Revision of Certain Water Quality Standards Applicable to Washington*, 81 FR 85417 (November 28, 2016).

EPA's selection of a 10^{-6} CRL is consistent with EPA's 2000 Methodology, which states that EPA intends to use the 10^{-6} level, which reflects an appropriate risk for the general population, when promulgating water quality criteria for states and tribes.⁶⁴ Additionally, many of Washington's rivers are in the Columbia River basin, upstream of Oregon's portion of the Columbia River. Oregon's criteria for PCBs and other pollutants are based on an FCR of 175 g/day and a CRL of 10^{-6} . EPA's final Federal HHC for Washington using a CRL of 10^{-6} along with an FCR of 175 g/day helps ensure that Washington's criteria will provide for the attainment and maintenance of Oregon's downstream WQS as required by 40 CFR 131.10(b).

As noted in EPA's 2016 final rule for Washington,⁶⁵ several tribes in Washington have treaty-reserved rights to fish on waters throughout the State. Consistent with those rights, tribal members catch and consume fish for their subsistence. EPA determined that a 10^{-6} CRL was appropriate independent of treaty rights, for the reasons explained in this section and EPA's Response to Comment document in the docket for this rule. Nonetheless, EPA's selection of a 10^{-6} CRL is protective of tribal members exercising their legal right to harvest and consume fish and shellfish at subsistence levels.⁶⁶

Some commenters asserted that EPA's use of a CRL of 10^{-6} is consistent with EPA's guidance and national precedent. These commenters agreed with EPA's proposal of HHC for PCBs based on a CRL of 10^{-6} paired with an FCR of 175 g/day and asserted that it violates the CWA and civil rights to expose high fish consumers to a higher cancer risk due to PCBs. Commenters stated that EPA did not show why Washington's criteria that it previously disapproved in 2016 were protective in 2019. Finally, commenters asserted that upstream pollution impacts the Spokane Tribe's ability to safely exercise their treaty reserved fishing rights and EPA's proposed PCB criteria are closer to the Tribe's criteria and therefore more

⁶⁴ EPA 2000 Methodology, p. 2-6. The Methodology recommends that states set human health criteria CRLs for the target general population at either 10^{-5} or 10^{-6} (p. 2-6) and also notes that states and authorized tribes can always choose a more stringent risk level, such as 10^{-7} (p. 1-12).

⁶⁵ 81 FR 85422-26 (November 28, 2016).

⁶⁶ In 2016, tribes in Washington State generally viewed 175 g/day as a compromise minimum consumption rate so long as it is coupled with a CRL of 10^{-6} . 2016 Partial Approval/Disapproval p. 15.

likely to provide for downstream protection. Commenters also state that use of a CRL of 10^{-6} to derive HHC for Washington addresses the potential for synergistic toxicity from exposure to multiple toxins.

Other commenters asserted that EPA's use of a 10^{-6} CRL is inconsistent with EPA's guidance and longstanding policy on acceptable risk levels. These commenters stated that EPA accepts CRLs of 10^{-6} or 10^{-5} , provided the median FCR for highly exposed populations is protected to a 10^{-4} risk level, and pointed to prior EPA actions, including EPA's 2019 approval of HHC in Idaho, 2011 HHC approval in Oregon, and EPA's Clean Water Act national recommended 304(a) criteria that pair a 10^{-6} cancer risk level with a general population fish consumption rate rather than an FCR associated with high fish consumers. Some commenters characterized a CRL of 10^{-4} as effectively zero risk to a small population such as the tribal population in Washington. Other commenters argued that the CRL is a choice for states to make and that EPA was right to accept Washington's choice of a PCB-specific CRL in 2019 because Washington's 2016 PCB criteria strike a more appropriate balance between cost and human health protection, and EPA's proposed PCB criteria are not scientifically defensible or attainable with currently available technology. Some commenters raised concerns that EPA's proposed criteria are below analytical method quantitation limits and therefore it is not clear how dischargers can comply with the criteria and this could be misleading to the public. Some commenters criticized EPA's cost estimates for the proposed rule, stating that testing methodology may improve, such that dischargers will then be out of compliance with permit limits, and stating that Washington is unlikely to adopt WQS variances to provide dischargers with relief. These commenters asserted that certain dischargers are already being pushed by EPA to use an unapproved PCB test method as the basis to design and install new treatment systems, and that EPA was wrong to assume that PCBs are not likely to be found in the effluent from minor facilities. Some commenters raised concerns that EPA and Washington State allow for the continued release of PCBs into the environment under the Toxic Substances Control Act, tribal

and Federal hatchery operations in Washington, and Washington's Model Toxics Control ACT, which in turn puts an unfair burden on dischargers in Washington to meet the proposed HHC for PCBs. Commenters also raised concerns that EPA has not shared the latest science evaluating the toxicity of inadvertently generated PCBs and there is ongoing scientific uncertainty with EPA's proposed PCB criteria that EPA has not sufficiently explained.

As noted above, in this final rule EPA is maintaining its proposed CRL of 10^{-6} , which Washington used in 2016 and EPA used in its 2016 Federal rule for all pollutants. With respect to the comments regarding utilizing that same CRL for PCBs, for the reasons that EPA further explained in the proposed rulemaking, the agency has concluded that Washington's PCB HHC are not protective of Washington's designated uses because of Washington's selected chemical-specific CRL, which is not based on a sound scientific rationale. For detailed responses to all comments received, including those which reiterate prior comments that EPA received on its 2015 proposed rulemaking for Washington and previously responded to, such as comments about the intersection of the CWA and the Toxic Substances Control Act with respect to PCBs, see EPA's Response to Comment document in the docket for this rule.

d. Relative Source Contribution

EPA recommends using an RSC for non-carcinogens and nonlinear carcinogens to account for sources of exposure other than drinking water and consumption of inland and nearshore fish and shellfish (see section II.B.d of this preamble). In its 2015 304(a) criteria recommendations, after evaluating information on chemical uses, properties, occurrences, releases to the environment and regulatory restrictions, EPA developed chemical-specific RSCs for non-carcinogens and nonlinear carcinogens ranging from 0.2 (20 percent) to 0.8 (80 percent)

following the Exposure Decision Tree approach described in EPA's 2000 Human Health Methodology.^{67,68}

When EPA promulgated HHC for Washington in 2016, EPA adjusted RSC values using a ratio of the national dataset characterizing all FCRs versus inland and nearshore-only FCRs derived from the NHANES dataset. EPA then applied this ratio to the proportion of the RfD reserved for inland and nearshore fish consumption in the RSC, and used this adjustment to account for double-counted potential exposure to certain chemicals in certain anadromous fish species (e.g., salmon). This approach involves the following assumptions:

- The pollutant concentrations in anadromous fish are the same as those in inland and nearshore fish; and
- The ratio of all fish to inland and nearshore fish from NHANES data approximates the ratio of inland, nearshore, and anadromous fish to just inland and nearshore fish from Columbia River Inter-Tribal Fish Commission (CRITFC)⁶⁹ data (since CRITFC data were used to derive the 175 g/day FCR).

At the 90th percentile rate of consumption, the national adult consumption rate from NHANES data for all fish is 53 g/day and 22 g/day for inland and nearshore-only fish, or a ratio of 2.4.

Applying this to an RSC of 0.2 yields 0.48, or 0.5 rounding to a single decimal place. Because the 175 g/day FCR includes some but not all marine species, EPA decided to use this approach to adjust the RSC values. However, EPA only adjusted RSC values to 0.5 for criteria calculations previously using an RSC between 0.2 and 0.5. Criteria derived using an RSC greater than 0.5 remained unchanged. EPA is using these same 2016 RSCs to derive HHC for Washington in this

⁶⁷ USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. <https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf>.

⁶⁸ Final Updated Ambient Water Quality Criteria for the Protection of Human Health, (80 FR 36986, June 29, 2015). See also: USEPA. 2015. Final 2015 Updated National Recommended Human Health Criteria. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. <https://www.epa.gov/wqc/human-health-water-quality-criteria>.

⁶⁹ *Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin* (CRITFC 1994).

final rule, having no new data or information to support revising RSCs. The inclusion of protective RSCs in the development of HHC is a science-based decision that protects human health by ensuring that a person's exposure to multiple sources of a chemical is accounted for. See Table 1, column B2 of this preamble for a list of EPA's RSCs by pollutant.

Some commenters asserted that use of an RSC of 1 is scientifically indefensible and that returning to EPA's 2016 approach of using an RSC equal to or less than 0.8 will ensure that the HHC consider other potential exposures. Commenters stated that tribes are regularly exposed to toxins through other routes of exposure in addition to fish consumption, such as dermal exposure. Commenters agreed with EPA's statement in the proposed rule that the choice of cancer risk level (CRL) is irrelevant to the choice of RSC since these inputs are for mutually exclusive categories of pollutants (carcinogens vs. non-carcinogens).

Other commenters asserted that the RSC value is a discretionary risk management decision and there is no regulatory requirement to examine multiple exposure routes when developing HHC. Commenters also stated that the criteria are only intended to protect for risks related to surface water exposure, i.e., fish and water. Some commenters asserted that it is arbitrary for EPA to use an RSC less than 1 when the FCR includes all fish. Other commenters pointed to prior EPA actions, including EPA's 2011 HHC approval in Oregon, and EPA's 2013 approval of HHC for the Spokane Tribe, to assert that EPA has approved HHC that rely on an RSC of 1. Finally, some commenters state that EPA's use of RSCs in the drinking water program under the Safe Drinking Water Act (SDWA) is different than using them for WQS since SDWA allows for consideration of cost in setting the final regulatory limits.

As explained in the proposed rulemaking, EPA determined that Washington's use of an RSC value of 1 to derive HHC is not based on sound scientific rationale as it apportioned the entire "safe" dose of certain chemicals to drinking water and fish consumption, ignoring other sources of those chemicals. While EPA acknowledges the comments indicating that it has previously approved WQS where states and authorized tribes utilized an RSC of 1 to develop

certain HHC, in those prior actions, EPA only approved HHC that used an RSC of 1 if EPA had not yet updated its own corresponding national recommended 304(a) criteria to reflect chemical-specific RSC values following the Exposure Decision Tree approach described in the 2000 Methodology. Without updated national recommended 304(a) criteria, states and tribes did not yet have the benefit of EPA's thorough review of exposure information that now exists since EPA updated its national HHC recommendations in 2015. Since the 2015 recommended HHC updates, EPA has encouraged all states to consider the latest science reflected in EPA's 2015 HHC recommendations during the triennial review of state WQS and update their HHC to incorporate appropriate RSCs. For detailed responses to all comments received, see EPA's Response to Comment document in the docket for this rule.

e. Pollutant-Specific Bioaccumulation Factors

Where data are available, EPA uses BAFs to account for the uptake and retention of waterborne chemicals by aquatic organisms from all surrounding media and to ensure that resulting criteria are science-based and protect designated uses for human health. Consistent with the 2016 Federal rule for Washington,⁷⁰ EPA is finalizing HHC for Washington by applying the trophic level four BAF from the 2015 CWA section 304(a) recommended HHC updates in conjunction with the 175 g/day FCR.⁷¹

Some commenters asserted that the choice of BCFs versus BAFs is a science-based rather than risk management decision, and that EPA is appropriately following the science in applying BAFs in this rule. These commenters asserted that BCFs undercount the amount of chemicals in fish, and EPA disregarded science and its own guidance when it approved BCF-based HHC in 2019.

⁷⁰ *Revision of Certain Water Quality Standards Applicable to Washington*, 81 FR 85417 (November 28, 2016).

⁷¹ Because the surveyed population upon which the 175 g/day FCR is based consumed almost exclusively trophic level four fish (i.e., predator fish species), EPA used the trophic level four BAF from the 2015 CWA section 304(a) HHC updates in conjunction with the 175 g/day FCR, in order to derive protective criteria. See *Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin* (CRITFC 1994).

Other commenters asserted that Washington's choice to use BCFs rather than BAFs was a sound science policy choice. These commenters asserted that BCFs are based on sound scientific principles and state that EPA has previously approved HHC that rely on BCFs. Commenters asserted that EPA's national recommended BAFs are just guidance, that they overestimate bioaccumulation and therefore lead to overly stringent HHC, and that they are insufficiently explained such that it is not possible to determine if they are appropriate for Washington. Some commenters asserted that both BAFs and BCFs are influenced by the local environment (e.g., food web structure, water temperature, dissolved carbon) and therefore cannot be based on a single set of assumptions for all waters.

Regarding the comments supporting the use of BCFs, as explained in the proposed rule, the use of BCFs rather than BAFs, where BAF data are available, to calculate the HHC is inconsistent with sound scientific rationale on the bioaccumulation of pollutants. EPA has considered the comments received on its selected BAFs and reiterates its explanation in the proposed rule that it does not have new data or information to support an alternative to its 2016 decision to use the trophic level four BAFs, given that the species commonly consumed in Washington are trophic level four fish (e.g., salmon). For certain pollutants for which science-based BAFs are not currently available, EPA is finalizing HHC using the BCFs from its updated CWA section 304(a) recommended HHC for those pollutants as the best available scientific information. See Table 1, columns B4 and B5 of this preamble for a list of EPA's bioaccumulation factors by pollutant. For detailed responses to all comments received, see EPA's Response to Comment document in the docket for this rule.

C. Final Human Health Criteria for Washington

EPA is finalizing 141 HHC for 72 different pollutants (70 organism-only criteria and 71 water-plus-organism criteria) to protect the applicable designated uses of Washington's waters (see Table 1 of this preamble). The final HHC are the same criteria that EPA promulgated in 2016. The water-plus-organism criteria in column C1 of Table 1 of this preamble, are the

applicable criteria for any waters that include the Domestic Water use (domestic water supply) defined in Washington's WQS (WAC 173-201A-600). The organism-only criteria in column C2 of Table 1 of this preamble, are the applicable criteria for any waters that do not include the Domestic Water use (domestic water supply) and that Washington defines at WAC 173-201A-600 and 173-201A-610 as the following:

- Fresh waters – Harvesting (fish harvesting), and Recreational Uses;
- Marine waters – Shellfish Harvesting (shellfish—clam, oyster, and mussel—harvesting), Harvesting (salmonid and other fish harvesting, and crustacean and other shellfish—crabs, shrimp, scallops, etc.—harvesting), and Recreational Uses.

Table 1. Final Human Health Criteria for Washington

	A		B					C	
	Chemical	CAS Number	Cancer Slope Factor, CSF (per mg/kg·d) (B1)	Relative Source Contribution, RSC (-) (B2)	Reference Dose, RfD (mg/kg·d) (B3)	Bio-accumulation Factor (L/kg tissue) (B4)	Bio-concentration Factor (L/kg tissue) (B5)	Water & Organisms (µg/L) (C1)	Organisms Only (µg/L) (C2)
1	1,1,1-Trichloroethane	71556	-	0.50	2	10	-	20,000	50,000
2	1,1,2,2-Tetrachloroethane	79345	0.2	-	-	8.4	-	0.1	0.3
3	1,1,2-Trichloroethane	79005	0.057	-	-	8.9	-	0.35	0.90
4	1,1-Dichloroethylene	75354	-	0.50	0.05	2.6	-	700	4,000
5	1,2,4-Trichlorobenzene	120821	0.029	-	-	430	-	0.036	0.037
6	1,2-Dichlorobenzene	95501	-	0.50	0.3	82	-	700	800
7	1,2-Dichloroethane	107062	0.0033	-	-	1.9	-	8.9	73
8	1,2-Diphenylhydrazine	122667	0.8	-	-	27	-	0.01	0.02
9	1,2-Trans-Dichloroethylene	156605	-	0.50	0.02	4.7	-	200	1,000
10	1,3-Dichlorobenzene	541731	-	0.50	0.002	190	-	2	2
11	1,3-Dichloropropene	542756	0.122	-	-	3.0	-	0.22	1.2
12	1,4-Dichlorobenzene	106467	-	0.50	0.07	84	-	200	200
13	2,4-Dichlorophenol	120832	-	0.50	0.003	48	-	10	10
14	2,4-Dinitrophenol	51285	-	0.50	0.002	4.4	-	30	100
15	2-Chloronaphthalene	91587	-	0.80	0.08	240	-	100	100
16	2-Methyl-4,6-Dinitrophenol	534521	-	0.50	0.0003	10	-	3	7
17	4,4'-DDD	72548	0.24	-	-	240,000	-	7.9E-06	7.9E-06
18	4,4'-DDE	72559	0.167	-	-	3,100,000	-	8.8E-07	8.8E-07
19	4,4'-DDT	50293	0.34	-	-	1,100,000	-	1.2E-06	1.2E-06
20	Acenaphthene	83329	-	0.50	0.06	510	-	30	30
21	Aldrin	309002	17	-	-	650,000	-	4.1E-08	4.1E-08
22	alpha-BHC	319846	6.3	-	-	1,500	-	4.8E-05	4.8E-05
23	alpha-Endosulfan	959988	-	0.50	0.006	200	-	6	7
24	Anthracene	120127	-	0.50	0.3	610	-	100	100
25	Antimony	7440360	-	0.50	0.0004	-	1	6	90
26	Benzo(a) Anthracene	56553	0.73	-	-	3,900	-	0.00016	0.00016
27	Benzo(a) Pyrene	50328	7.3	-	-	3,900	-	1.6E-05	1.6E-05
28	Benzo(b) Fluoranthene	205992	0.73	-	-	3,900	-	0.00016	0.00016
29	Benzo(k) Fluoranthene	207089	0.073	-	-	3,900	-	0.0016	0.0016
30	beta-BHC	319857	1.8	-	-	180	-	0.0013	0.0014
31	Bis(2-Ethylhexyl) Phthalate	117817	0.014	-	-	710	-	0.045	0.046
32	Bromoform	75252	0.0045	-	-	8.5	-	4.6	12
33	Butylbenzyl Phthalate	85687	0.0019	-	-	19,000	-	0.013	0.013
34	Chlordane	57749	0.35	-	-	60,000	-	2.2E-05	2.2E-05
35	Chlorobenzene	108907	-	0.50	0.02	22	-	100	200
36	Chlorodibromomethane	124481	0.04	-	-	5.3	-	0.60	2.2
37	Chloroform	67663	-	0.50	0.01	3.8	-	100	600
38	Chrysene	218019	0.0073	-	-	3,900	-	0.016	0.016
39	Cyanide	57125	-	0.50	0.0006	-	1	9	100

40	Dibenzo(a,h) Anthracene	53703	7.3	-	-	3,900	-	1.6E-05	1.6E-05
41	Dichlorobromomethane	75274	0.034	-	-	4.8	-	0.73	2.8
42	Dieldrin	60571	16	-	-	410,000	-	7.0E-08	7.0E-08
43	Diethyl Phthalate	84662	-	0.50	0.8	920	-	200	200
44	Dimethyl Phthalate	131113	-	0.50	10	4,000	-	600	600
45	Di-n-Butyl Phthalate	84742	-	0.50	0.1	2,900	-	8	8
46	Endosulfan Sulfate	1031078	-	0.50	0.006	140	-	9	-
47	Endrin	72208	-	0.80	0.0003	46,000	-	0.002	0.002
48	Ethylbenzene	100414	-	0.50	0.022	160	-	29	31
49	Fluoranthene	206440	-	0.50	0.04	1,500	-	6	6
50	Fluorene	86737	-	0.50	0.04	710	-	10	10
51	gamma-BHC; Lindane	58899	-	0.50	0.0047	2,500	-	0.43	0.43
52	Heptachlor	76448	4.1	-	-	330,000	-	3.4E-07	3.4E-07
53	Heptachlor Epoxide	1024573	5.5	-	-	35,000	-	2.4E-06	2.4E-06
54	Hexachlorobenzene	118741	1.02	-	-	90,000	-	5.0E-06	5.0E-06
55	Hexachlorobutadiene	87683	0.04	-	-	1,100	-	0.01	0.01
56	Hexachlorocyclopentadiene	77474	-	0.50	0.006	1,300	-	1	1
57	Hexachloroethane	67721	0.04	-	-	600	-	0.02	0.02
58	Indeno(1,2,3-cd) Pyrene	193395	0.73	-	-	3,900	-	0.00016	0.00016
59	Methyl Bromide	74839	-	0.50	0.02	1.4	-	300	-
60	Methylene Chloride	75092	0.002	-	-	1.6	-	10	100
61	Nickel	7440020	-	0.50	0.02	-	47	80	100
62	Nitrobenzene	98953	-	0.50	0.002	3.1	-	30	100
63	Pentachlorophenol (PCP)	87865	0.4	-	-	520	-	0.002	0.002
64	Phenol	108952	-	0.50	0.6	1.9	-	9,000	70,000
65	Polychlorinated Biphenyls (PCBs)		2	-	-	-	31,200	^a 7E-06	^a 7E-06
66	Pyrene	129000	-	0.50	0.03	860	-	8	8
67	Selenium	7782492	-	0.50	0.005	-	4.8	60	200
68	Tetrachloroethylene	127184	0.0021	-	-	76	-	2.4	2.9
69	Toluene	108883	-	0.50	0.0097	17	-	72	130
79	Trichloroethylene	79016	0.05	-	-	13	-	0.3	0.7
71	Vinyl Chloride	75014	1.5	-	-	1.7	-	-	0.18
72	Zinc	7440666	-	0.50	0.3	-	47	1,000	1,000
^a	This criterion applies to total PCBs (e.g., the sum of all congener or isomer or homolog or Aroclor analyses).								

D. Applicability

Under the CWA, Congress gave states primary responsibility for developing and adopting WQS for their navigable waters (CWA section 303(a)-(c)). Although EPA is finalizing revised HHC for Washington, Washington continues to have the option to adopt and submit to EPA newly revised HHC for the State's waters consistent with CWA section 303(c) and EPA's

implementing regulations at 40 CFR part 131. If, subsequent to this final rule, Washington adopts and submits revised HHC, EPA's federally promulgated criteria will remain applicable for purposes of the CWA until EPA withdraws the federally promulgated criteria (40 CFR 131.21(c)). EPA would undertake such a rulemaking to withdraw the Federal criteria if and when Washington adopts and EPA approves corresponding State criteria that meet the requirements of section 303(c) of the CWA and EPA's implementing regulations at 40 CFR part 131.

E. Alternative Regulatory Approaches and Implementation Mechanisms

The Federal WQS regulation at 40 CFR part 131 provides several tools that Washington has available to use at its discretion when implementing or deciding how to implement these HHC. Among other things, EPA's WQS regulation: (1) specifies how states and authorized tribes establish, modify, or remove designated uses (40 CFR 131.10); (2) specifies the requirements for establishing criteria to protect designated uses, including criteria modified to reflect site-specific conditions (40 CFR 131.11); (3) authorizes and provides a regulatory framework for states and authorized tribes to adopt WQS variances where it is not feasible to attain the applicable WQS at that time (40 CFR 131.14); and (4) allows states and authorized tribes to authorize the use of compliance schedules in National Pollutant Discharge Elimination System (NPDES) permits to meet water quality-based effluent limits (WQBELs) derived from the applicable WQS (40 CFR 131.15). Each of these approaches is discussed in more detail in the next sections. Whichever approach a state pursues, however, all NPDES permits would need to comply with EPA's regulations at 40 CFR 122.44(d)(1)(i).

a. Designated Uses

EPA's HHC apply to waters that Washington has designated for the following:

- Fresh waters – Harvesting (fish harvesting), Domestic Water (domestic water supply), and Recreational Uses;
- Marine waters – Shellfish Harvesting (shellfish—clam, oyster, and mussel—harvesting), Harvesting (salmonid and other fish harvesting, and crustacean and

other shellfish—crabs, shrimp, scallops, etc.—harvesting), and Recreational Uses (see WAC 173-201A-600 and WAC 173-201A-610).

The Federal regulation at 40 CFR 131.10(g) provides requirements for establishing, modifying, and removing designated uses when attaining the use is not feasible based on one of the six factors specified in the regulation. If Washington removes a use and adopts the highest attainable use,⁷² the State must also adopt criteria to protect the newly designated highest attainable use consistent with 40 CFR 131.11. It is possible that criteria other than the federally promulgated criteria would protect the highest attainable use. If EPA found removal or modification of the designated use and the adoption of the highest attainable use and criteria to protect that use to be consistent with CWA section 303(c) and the implementing regulation at 40 CFR part 131, the agency would approve the revised WQS. EPA would then undertake a rulemaking to withdraw the corresponding Federal WQS for the relevant water(s).

b. *WQS Variances*

Washington's WQS provide authority to apply WQS variances when implementing federally promulgated HHC, as long as such WQS variances are adopted consistent with 40 CFR 131.14 and submitted to EPA for review under CWA section 303(c). The Federal regulation at 40 CFR 131.3(o) defines a WQS variance as a time-limited designated use and criterion, for a specific pollutant or water quality parameter, that reflects the highest attainable condition during the term of the WQS variance. A WQS variance may be appropriate if attaining the use and criterion would not be feasible during the term of the WQS variance because of one of the seven factors specified in 40 CFR 131.14(b)(2)(i)(A). These factors include a situation where NPDES permit limits more stringent than technology-based controls would result in substantial and

⁷² If a state or authorized tribe adopts a new or revised WQS based on a required use attainability analysis, then it must also adopt the highest attainable use (40 CFR 131.10(g)). The highest attainable use is the modified aquatic life, wildlife, or recreation use that is both closest to the uses specified in section 101(a)(2) of the CWA and attainable, based on the evaluation of the factor(s) in 40 CFR 131.10(g) that preclude(s) attainment of the use and any other information or analyses that were used to evaluate attainability. There is no required highest attainable use where the state demonstrates the relevant use specified in section 101(a)(2) of the Act and sub-categories of such a use are not attainable (see 40 CFR 131.3(m)).

widespread economic and social impact. WQS variances adopted in accordance with 40 CFR 131.14 (including a public hearing consistent with 40 CFR 25.5) provide a flexible but defined pathway for states and authorized tribes to issue NPDES permits with limits that are based on the highest attainable condition during the term of the WQS variance. This allows dischargers to make water quality improvements when the WQS is not immediately attainable but may be in the future. When adopting a WQS variance, states and authorized tribes specify the interim requirements of the WQS variance by identifying a quantitative expression that reflects the highest attainable condition (HAC) during the term of the WQS variance, establishing the term of the WQS variance, and describing the pollutant control activities expected to occur over the specified term of the WQS variance. WQS variances provide a legal avenue by which NPDES permit limits can be written to comply with the WQS variance rather than the underlying WQS for the term of the WQS variance. If dischargers are still unable to meet the WQBELs derived from the applicable WQS once a WQS variance term is complete, the regulation allows the State to adopt a subsequent WQS variance if it is adopted consistent with 40 CFR 131.14. EPA is finalizing HHC that apply to use designations that Washington has already established.

Washington's WQS regulations currently include provisions to use WQS variances when implementing criteria (see WA 173-210A-420), as long as such WQS variances are adopted consistent with 40 CFR 131.14 and approved by EPA. Washington may use the State's EPA-approved WQS variance procedures when adopting such WQS variances.

c. NPDES Permit Compliance Schedules

EPA's regulations at 40 CFR 122.47 and 131.15 address how permitting authorities can use schedules for compliance with a limit in the NPDES permit if the discharger needs additional time to undertake actions like facility upgrades or operation changes to meet a WQBEL based on the applicable WQS. EPA's regulation at 40 CFR 122.47 allows a permitting authority to include a compliance schedule in the NPDES permit, when appropriate and where authorized by the state, to provide a discharger with additional time to meet a WQBEL implementing applicable

WQS. EPA's regulation at 40 CFR 131.15 requires that a state that intends to allow the use of NPDES permit compliance schedules adopt specific provisions authorizing their use and obtain EPA approval under CWA section 303(c) to ensure that a decision to allow a permit compliance schedule is transparent and allows for public input.⁷³ EPA has approved Washington's State law provision authorizing the use of permit compliance schedules (see WAC-173-201A-510(4)), consistent with 40 CFR 131.15. Washington's compliance schedule authorizing provision is not affected by this rule. Washington is authorized to grant permit compliance schedules, as appropriate, based on the Federal HHC in Washington, if such permit compliance schedules are consistent with EPA's permitting regulation at 40 CFR 122.47.

IV. Economic Analysis

EPA focused its economic analysis on the potential cost impacts to current holders of individual NPDES permits (point sources) and the costs the State of Washington may bear to develop Total Maximum Daily Loads (TMDLs) for waters newly identified as impaired under CWA section 303(d) using the revised WQS. Costs might also arise to holders of general permits⁷⁴ should the State modify those permits in some manner as a result of the revised WQS. Costs might also arise to sectors whose operations are nonpoint sources of pollutants through implementation of TMDLs or through other voluntary, incentivized, or State-imposed controls. This rule does not directly regulate nonpoint sources and under the CWA states are responsible for the regulation of nonpoint sources. EPA recognizes that controls for nonpoint sources may be part of future TMDLs, but any such future decisions will be made by the State. Nonpoint sources are intermittent, variable, and occur under hydrologic or climatic conditions associated with precipitation events. Data to model and evaluate the potential cost impacts associated with nonpoint sources were not available and any estimate would be too uncertain to be informative. EPA also did not estimate potential sediment remediation costs for this analysis.

⁷³ 80 FR 51022 (August 21, 2015).

⁷⁴ General permits typically focus on best management practices.

These WQS may serve as a basis for development of NPDES permit limits. Washington has NPDES permitting authority and retains considerable discretion in implementing standards. EPA evaluated the potential costs to NPDES dischargers associated with State implementation of EPA's criteria. This analysis is documented in "Economic Analysis for Restoring Protective Human Health Criteria in Washington," which can be found in the record for this rule. Any NPDES-permitted facility that discharges pollutants for which the revised HHC are more stringent than the applicable aquatic life criteria (or for which HHC are the only applicable criteria) could potentially incur compliance costs. The types of affected facilities could include industrial facilities and POTWs discharging wastewater to surface waters (i.e., point sources).

A. Identifying Affected Entities

EPA identified 406 point source facilities that could ultimately be affected by this rule. Of these potentially affected facilities, 73 are major dischargers and 333 are minor dischargers. EPA did not include general permit facilities in its analysis because data for such facilities are limited and requirements typically focus on best management practices. Of the potentially affected facilities, EPA evaluated a sample of 18 major facilities. Minor facilities are less likely to incur costs as a result of implementation of the rule because of the reduced potential for significant presence of toxic pollutants in their effluent. EPA did not have effluent data on toxic pollutants to evaluate minor facilities for this analysis. Table 2 summarizes these potentially affected facilities by type and category.

Table 2. Potentially Affected Facilities			
Category	Minor	Major	All
Municipal	169	44	213
Industrial	164	29	193
Total	333	73	406

B. Method for Estimating Costs

EPA evaluated the two major municipal facilities with design flows greater than 100 mgd and the largest industrial facility, to attempt to capture the facilities with the potential for the

largest costs. For the remaining major facilities, EPA evaluated a random sample of facilities to represent discharger type and category. For all sample facilities, EPA evaluated existing baseline permit conditions, reasonable potential to exceed HHC based on the rulemaking, and potential to exceed projected effluent limitations based on the last three years of effluent monitoring data (if available). Only compliance actions and costs that would be needed above the baseline level of controls are attributable to the rulemaking.

EPA assumes that dischargers would pursue the least cost means of compliance with WQBELs. Compliance actions attributable to the rulemaking may include pollution prevention, end-of-pipe treatment, and alternative compliance mechanisms (e.g., WQS variances). EPA annualizes capital costs, including study (e.g., WQS variance) and program (e.g., pollution prevention) costs, over 20 years using discount rates of 3 percent and 7 percent to obtain total annual costs per facility. To obtain an estimate of total costs to point sources, EPA extrapolates the annualized costs for the random sample based on the flow volume for the sample facilities and the flow volume for all facilities.

C. Results

Based on the results for 18 sample facilities across 10 industrial and municipal categories,⁷⁵ EPA did not identify any incremental costs to any major point source discharges of process wastewater from POTWs or industrial facilities attributable to EPA's criteria revisions. This does not mean that EPA anticipates there would be no costs to point sources over time to implement controls or modify processes to meet future permit limits, only that available data do not indicate the immediate need for the facilities evaluated. It would be highly speculative to attempt to estimate potential costs either based on the possibility of measuring pollutant levels at lower levels as a result of future requirements or future technology, or based on changes to facility operations or practices. Should the need to consider advanced treatment or other

⁷⁵ Ten industrial categories (coal mining, food and kindred products, paper and allied products, chemicals and allied products, petroleum refining and related industries, primary metal industries, fabricated metal products, electric, gas and sanitary services, and national security and international affairs) and municipal POTWs.

substantial costs arise in the future, there are mechanisms such as WQS variances in place which may consider cost and feasibility in the application of protective criteria, and alternative permit limits may be derived to avoid excessive costs. EPA will work with the State of Washington and with stakeholders on a continuing basis to assess the possibility of economically significant future costs of compliance. If such costs arise, EPA will provide guidance for applying alternative compliance mechanisms to minimize costs.

One important contributing factor to examining point source costs is the limitations of required analytical methods to measure chemical concentrations in effluents. Nearly half of pollutant parameters addressed in this rule have analytical quantitation limits that are above both the criteria currently in place and EPA's criteria. PCBs are a good example. The current criterion in place is 170 picograms per liter (pg/L) and EPA's criterion is 7 pg/L. However, the State identifies the analytical detection limit for effluent measurement as 65,000 pg/L as the means to evaluate compliance. EPA has completed a multi-laboratory validation of a new analytical method for PCBs (method 1628) that has an average analytical quantitation limit for each PCB congener of approximately 2,000 pg/L, which is a substantial improvement over the current regulatory method, but still well above either the criterion currently in place or EPA's criterion. As a general matter, analytical methods and quantitation limits are subject to change over time. As such, it is important that WQS reflect the necessary level of protection regardless of contemporary limitations of analytical methods.

EPA also evaluated potential administrative costs to the State for developing additional TMDLs under CWA section 303(d) for any waters that are newly identified as impaired as a result of EPA's criteria. Using available ambient monitoring data, EPA compared pollutant concentrations to the baseline and revised criteria, identifying waterbodies that may be incrementally impaired (i.e., impaired under EPA's criteria but not under the baseline). EPA identified 32 impairments under the baseline criteria and 61 under the revised criteria, resulting in 29 potential incremental impairments. The estimated total annual costs for TMDL

development range from \$100,000 to \$182,000, at a 3 percent discount rate, based on single-cause single-waterbody TMDL development costs. Actual costs may be reduced if the State develops multi-cause or multi-waterbody TMDLs.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. While actions to implement these WQS could entail additional paperwork burden, this action does not directly contain any information collection, reporting, or record-keeping requirements. OMB has previously approved the information collection activities contained in the existing regulation at 40 CFR part 131 and has assigned OMB control number 2040-0049.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. Small entities, such as small businesses or small governmental jurisdictions, are not directly regulated by this rule. EPA-promulgated WQS are implemented through various water quality control programs including the NPDES program, which limits discharges to navigable waters except in compliance with a NPDES permit. CWA section 301(b)(1)(C) and EPA's implementing regulations at 40 CFR 122.44(d)(1) introductory text and (d)(1)(i) provide that all NPDES permits shall include any limits on discharges that are necessary to meet applicable WQS. Thus, under the CWA, EPA's promulgation of WQS establishes standards that the State

implements through the NPDES permit process. While the State has discretion in developing discharge limits, as needed to meet the WQS, those limits, per regulations at 40 CFR 122.44(d)(1)(i), “must control all pollutants or pollutant parameters (either conventional, nonconventional, or toxic pollutants) which the Director determines are or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any [s]tate water quality standard, including [s]tate narrative criteria for water quality.” As a result of this action, the State of Washington will need to ensure that permits it issues include any limitations on discharges necessary to comply with the WQS established in this final rule. In doing so, the State will have a number of choices associated with permit writing. While Washington’s implementation of the rule may ultimately result in new or revised permit conditions for some dischargers, including small entities, EPA’s action, by itself, does not impose any of these requirements on small entities; that is, these requirements are not self-implementing.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

E. Executive Order 13132: Federalism

Under the technical requirements of Executive Order 13132, the EPA has determined that this rule may not have federalism implications but believes that the consultation requirements of the Executive order have been satisfied in any event. This rule does not alter Washington’s considerable discretion in implementing these WQS, nor does it preclude Washington from adopting WQS that EPA concludes meet the requirements of the CWA after promulgation of this final rule.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action has tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. This rule could affect federally recognized Indian tribes in Washington because the numeric criteria for Washington will apply to waters adjacent to (or upstream or downstream of) the tribal waters. Additionally, there are six federally recognized Indian tribes in the Columbia River Basin located in the States of Oregon and Idaho that this rule could affect because their waters could affect or be affected by the water quality of Washington's downstream or upstream waters.

EPA consulted with tribal governments under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to ensure meaningful and timely input into its development. In August 2021, EPA held coordination and consultation sessions with tribal environmental staff and leadership to share information, hear their views and answer questions on the rulemaking. Representatives from 17 tribes and two tribal consortia participated in two leadership meetings with EPA held in August 2021. Additionally, EPA conducted tribal consultation and coordination activities on the proposed rulemaking from March 29, 2022, through June 3, 2022. During these meetings, the tribes repeatedly asked EPA to reinstate the 2016 Federal HHC for Washington, which EPA is doing in this final rule.

A Summary of EPA's Consultation, Coordination, and Outreach with Federally Recognized Tribes on the Restoration of Protective Human Health Criteria for Washington is available in the docket for this final rule.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in section II.B of this preamble,

in which EPA recommends that HHC be designed to reduce the risk of adverse cancer and non-cancer effects occurring from lifetime exposure to pollutants through the ingestion of drinking water and consumption of fish/shellfish obtained from inland and nearshore waters. EPA's HHC for Washington are similarly based on reducing the chronic health effects occurring from lifetime exposure and therefore are expected to be protective of a person's exposure during both childhood and adult years.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866. This action establishes CWA HHC for waters under the State of Washington's jurisdiction.

I. National Technology Transfer and Advancement Act of 1995

This rule does not involve technical standards.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or Indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained below.

1. Introduction

EPA defines Environmental Justice (EJ) as the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the

development, implementation and enforcement of environmental laws, regulations and policies.⁷⁶ Three Executive orders (E.O. 12898,⁷⁷ 13985,⁷⁸ and 14008⁷⁹) advance EJ by calling on Federal agencies to identify and address disproportionate impacts on historically underserved, marginalized, and economically disadvantaged people. Additionally, EPA has expressed a commitment to conducting EJ analyses for rulemakings as described in the April 30, 2021, revisions to the Cross-State Air Pollution Rule (CSAPR).⁸⁰

EPA believes that this rule is not expected to have disproportionately high and adverse human health or environmental effects on low-income populations, people of color, or tribal populations, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). In its economic impact analysis, EPA only estimates administrative costs to the State of Washington to develop TMDLs and no incremental costs to point source discharges based on available data, as explained above in section IV of this preamble. Therefore, EPA does not anticipate that this rule will impose any additional costs or other negative impacts on tribes or other low income or disadvantaged communities.

⁷⁶ Fair treatment means that “no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental and commercial operations or programs and policies.” Meaningful involvement occurs when “1) potentially affected populations have an appropriate opportunity to participate in decisions about a proposed activity [e.g., rulemaking] that will affect their environment and/or health; 2) the public’s contribution can influence [the EPA’s rulemaking] decision; 3) the concerns of all participants involved will be considered in the decision-making process; and 4) [the EPA will] seek out and facilitate the involvement of those potentially affected.” A potential EJ concern is defined as “the actual or potential lack of fair treatment or meaningful involvement of minority populations, low-income populations, tribes, and tribal peoples in the development, implementation and enforcement of environmental laws, regulations and policies.” See “Guidance on Considering Environmental Justice During the Development of an Action,” Environmental Protection Agency, www.epa.gov/environmentaljustice/guidanceconsidering-environmental-justice-duringdevelopment-action. See also <https://www.epa.gov/environmentaljustice>.

⁷⁷ Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations. Available at <https://www.epa.gov/environmentaljustice/federal-actions-address-environmental-justice-minority-populations-and-low>, accessed October 6, 2021.

⁷⁸ Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (86 FR 7009, January 25, 2021). Available at <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>, accessed October 6, 2021.

⁷⁹ Tackling the Climate Crisis at Home and Abroad (86 FR 7619, February 1, 2021). Available at <https://www.federalregister.gov/documents/2021/02/01/2021-02177/tackling-the-climate-crisis-at-home-and-abroad>, accessed October 6, 2021.

⁸⁰ 86 FR 23054, 23162 (April 30, 2021) (“Going forward, EPA is committed to conducting environmental justice analysis for rulemakings based on a framework similar to what is outlined here, in addition to investigating ways to further weave environmental justice into the fabric of the rulemaking process including through enhanced meaningful engagement with environmental justice communities.”).

Instead, this action identifies and ameliorates disproportionately high and adverse human health effects on tribal communities, people of color and low-income populations in Washington by restoring HHC in Washington that are based on sound scientific rationale and protect high fish consumers.

Many groups in Washington, such as Asian, Pacific Islanders, and subsistence and recreational tribal and non-tribal fishers consume large amounts of fish and shellfish as part of traditionally influenced diets.⁸¹ The 2019 Reconsidered HHC currently expose these high fish consumers to greater risk from toxic pollutants because the criteria do not accurately account for pollutant bioaccumulation into fish and expose fish consumers to a greater risk of cancer from PCB exposure.

Environmental impacts to tribes may be considered under the category of EJ in recognition that tribes may at times be among the disadvantaged communities disproportionately impacted by environmental degradation. Where tribal communities are part of a larger non-tribal community, many of the EJ considerations are very similar to those of other disadvantaged groups. However, there is a very unique set of EJ considerations for tribes, particularly in this context where tribes are exercising their cultural practices and treaty-reserved rights outside of their reservations on state waters.

While the overall impacts to communities with EJ concerns are improved as a result of this rule, by relying on the fish consumption rates based on tribal data, this rule helps ensure that tribal members, in particular, and their treaty-protected activities and resources are protected.⁸² Specifically, this rule establishes HHC based on an FCR of 175 g/day reflective of regional tribal

⁸¹ Department of Ecology. *Fish Consumption Rates: Technical Support Document, A Review of Data and Information about Fish Consumption in Washington, Version 2.0 Final*. January 2013. Ecology Publication No. 12-09-058, p.18. <https://apps.ecology.wa.gov/publications/documents/1209058.pdf>.

⁸² 80 FR 55063 (September 14, 2015) (“In Washington, many tribes hold reserved rights to take fish for subsistence, ceremonial, religious, and commercial purposes, including treaty-reserved rights to fish at all usual and accustomed fishing grounds and stations in waters under state jurisdiction, which cover the majority of waters in the state. Such rights include not only a right to take those fish, but necessarily include an attendant right to not be exposed to unacceptable health risks by consuming those fish.”).

FCR survey data⁸³ to represent and protect higher fish consumers. In conjunction with the FCR, the rule uses a CRL of 10^{-6} to derive HHC for all cancer-causing pollutants, including PCBs, a rate which is protective of tribal members exercising their legal right to harvest and consume fish and shellfish at the 175 g/day level.

Central to working with tribes on their environmental issues and opportunities is government to government consultation, which is consistent with Executive Order 13175 (65 FR 67249, November 6, 2000). To ensure that this rule considers the interests and perspective of tribes, EPA engaged with tribes that may be affected by this action to receive meaningful and timely input from tribal officials. See section V.F of this preamble for a summary of tribal consultation.

In addition to Executive Orders 12898 and 13175, and in accordance with Title VI of the Civil Rights Act of 1964, each Federal agency shall ensure that all programs or activities receiving Federal financial assistance that affect human health or the environment do not directly, or through contractual or other arrangements, use criteria, methods, or practices that discriminate on the basis of race, color, or national origin. With that directive in mind, in August 2011 the Environmental Justice Interagency Working Group established a Title VI Committee to address the intersection of agencies' environmental justice efforts with their Title VI enforcement and compliance responsibilities. If Washington receives Federal funds for CWA implementation, they are legally prohibited from discriminating on the basis of race, color or national origin under Title VI when engaging in CWA implementation activities. Additionally, and in compliance with Executive Order 12898, EPA expects that Washington will consider disproportionately high adverse human health and environmental effects on minority and low-income populations when implementing this rule under the CWA.

K. Congressional Review Act (CRA)

⁸³ *Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin* (CRITFC 1994).

This action is subject to the CRA, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 131

Environmental protection, Indians-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, EPA amends 40 CFR part 131 as follows:

PART 131—WATER QUALITY STANDARDS

1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

Subpart D—Federally Promulgated Water Quality Standards

2. Amend § 131.45 by revising paragraph (b) to read as follows:

§ 131.45 Revision of certain Federal water quality criteria applicable to Washington.

* * * * *

(b) *Criteria for priority toxic pollutants in Washington.* The applicable human health criteria are shown in table 1 to this paragraph (b).

Table 1 to Paragraph (b)—Human Health Criteria for Washington

	A		B					C	
	Chemical	CAS Number	Cancer Slope Factor, CSF (per mg/kg·d) (B1)	Relative Source Contribution, RSC (-) (B2)	Reference Dose, RfD (mg/kg·d) (B3)	Bio-accumulation Factor (L/kg tissue) (B4)	Bio-concentration Factor (L/kg tissue) (B5)	Water & Organisms (µg/L) (C1)	Organisms Only (µg/L) (C2)
1	1,1,1-Trichloroethane	71556	-	0.50	2	10	-	20,000	50,000
2	1,1,2,2-Tetrachloroethane	79345	0.2	-	-	8.4	-	0.1	0.3
3	1,1,2-Trichloroethane	79005	0.057	-	-	8.9	-	0.35	0.90
4	1,1-Dichloroethylene	75354	-	0.50	0.05	2.6	-	700	4,000
5	1,2,4-Trichlorobenzene	120821	0.029	-	-	430	-	0.036	0.037
6	1,2-Dichlorobenzene	95501	-	0.50	0.3	82	-	700	800
7	1,2-Dichloroethane	107062	0.0033	-	-	1.9	-	8.9	73
8	1,2-Diphenylhydrazine	122667	0.8	-	-	27	-	0.01	0.02
9	1,2-Trans-Dichloroethylene	156605	-	0.50	0.02	4.7	-	200	1,000
10	1,3-Dichlorobenzene	541731	-	0.50	0.002	190	-	2	2
11	1,3-Dichloropropene	542756	0.122	-	-	3.0	-	0.22	1.2
12	1,4-Dichlorobenzene	106467	-	0.50	0.07	84	-	200	200
13	2,4-Dichlorophenol	120832	-	0.50	0.003	48	-	10	10
14	2,4-Dinitrophenol	51285	-	0.50	0.002	4.4	-	30	100
15	2-Chloronaphthalene	91587	-	0.80	0.08	240	-	100	100
16	2-Methyl-4,6-Dinitrophenol	534521	-	0.50	0.0003	10	-	3	7
17	4,4'-DDD	72548	0.24	-	-	240,000	-	7.9E-06	7.9E-06
18	4,4'-DDE	72559	0.167	-	-	3,100,000	-	8.8E-07	8.8E-07
19	4,4'-DDT	50293	0.34	-	-	1,100,000	-	1.2E-06	1.2E-06
20	Acenaphthene	83329	-	0.50	0.06	510	-	30	30
21	Aldrin	309002	17	-	-	650,000	-	4.1E-08	4.1E-08
22	alpha-BHC	319846	6.3	-	-	1,500	-	4.8E-05	4.8E-05
23	alpha-Endosulfan	959988	-	0.50	0.006	200	-	6	7
24	Anthracene	120127	-	0.50	0.3	610	-	100	100
25	Antimony	7440360	-	0.50	0.0004	-	1	6	90
26	Arsenic*	7440382	1.75	-	-	-	44	^a 0.018	^a 0.14
27	Benzo(a) Anthracene	56553	0.73	-	-	3,900	-	0.00016	0.00016
28	Benzo(a) Pyrene	50328	7.3	-	-	3,900	-	1.6E-05	1.6E-05
29	Benzo(b) Fluoranthene	205992	0.73	-	-	3,900	-	0.00016	0.00016
30	Benzo(k) Fluoranthene	207089	0.073	-	-	3,900	-	0.0016	0.0016
31	beta-BHC	319857	1.8	-	-	180	-	0.0013	0.0014
32	Bis(2-Chloro-1-Methylethyl) Ether**	108601	-	0.50	0.04	10	-	400	900
33	Bis(2-Ethylhexyl) Phthalate	117817	0.014	-	-	710	-	0.045	0.046
34	Bromoform	75252	0.0045	-	-	8.5	-	4.6	12
35	Butylbenzyl Phthalate	85687	0.0019	-	-	19,000	-	0.013	0.013
36	Chlordane	57749	0.35	-	-	60,000	-	2.2E-05	2.2E-05
37	Chlorobenzene	108907	-	0.50	0.02	22	-	100	200
38	Chlorodibromomethane	124481	0.04	-	-	5.3	-	0.60	2.2
39	Chloroform	67663	-	0.50	0.01	3.8	-	100	600
40	Chrysene	218019	0.0073	-	-	3,900	-	0.016	0.016

A			B					C	
	Chemical	CAS Number	Cancer Slope Factor, CSF (per mg/kg·d) (B1)	Relative Source Contribution, RSC (-) (B2)	Reference Dose, RfD (mg/kg·d) (B3)	Bio-accumulation Factor (L/kg tissue) (B4)	Bio-concentration Factor (L/kg tissue) (B5)	Water & Organisms (µg/L) (C1)	Organisms Only (µg/L) (C2)
41	Cyanide	57125	-	0.50	0.0006	-	1	9	100
42	Dibenzo(a,h) Anthracene	53703	7.3	-	-	3,900	-	1.6E-05	1.6E-05
43	Dichlorobromomethane	75274	0.034	-	-	4.8	-	0.73	2.8
44	Dieldrin	60571	16	-	-	410,000	-	7.0E-08	7.0E-08
45	Diethyl Phthalate	84662	-	0.50	0.8	920	-	200	200
46	Dimethyl Phthalate	131113	-	0.50	10	4,000	-	600	600
47	Di-n-Butyl Phthalate	84742	-	0.50	0.1	2,900	-	8	8
48	Endosulfan Sulfate	1031078	-	0.50	0.006	140	-	9	-
49	Endrin	72208	-	0.80	0.0003	46,000	-	0.002	0.002
50	Ethylbenzene	100414	-	0.50	0.022	160	-	29	31
51	Fluoranthene	206440	-	0.50	0.04	1,500	-	6	6
52	Fluorene	86737	-	0.50	0.04	710	-	10	10
53	gamma-BHC; Lindane	58899	-	0.50	0.0047	2,500	-	0.43	0.43
54	Heptachlor	76448	4.1	-	-	330,000	-	3.4E-07	3.4E-07
55	Heptachlor Epoxide	1024573	5.5	-	-	35,000	-	2.4E-06	2.4E-06
56	Hexachlorobenzene	118741	1.02	-	-	90,000	-	5.0E-06	5.0E-06
57	Hexachlorobutadiene	87683	0.04	-	-	1,100	-	0.01	0.01
58	Hexachlorocyclopentadiene	77474	-	0.50	0.006	1,300	-	1	1
59	Hexachloroethane	67721	0.04	-	-	600	-	0.02	0.02
60	Indeno(1,2,3-cd) Pyrene	193395	0.73	-	-	3,900	-	0.00016	0.00016
61	Methyl Bromide	74839	-	0.50	0.02	1.4	-	300	-
62	Methylene Chloride	75092	0.002	-	-	1.6	-	10	100
63	Methylmercury	22967926	-	2.7E-05	0.0001	-	-	-	^b 0.03 (mg/kg)
64	Nickel	7440020	-	0.50	0.02	-	47	80	100
65	Nitrobenzene	98953	-	0.50	0.002	3.1	-	30	100
66	Pentachlorophenol (PCP)	87865	0.4	-	-	520	-	0.002	0.002
67	Phenol	108952	-	0.50	0.6	1.9	-	9,000	70,000
68	Polychlorinated Biphenyls (PCBs)		2	-	-	-	31,200	^c 7E-06	^c 7E-06
69	Pyrene	129000	-	0.50	0.03	860	-	8	8
70	Selenium	7782492	-	0.50	0.005	-	4.8	60	200
71	Tetrachloroethylene	127184	0.0021	-	-	76	-	2.4	2.9
72	Toluene	108883	-	0.50	0.0097	17	-	72	130
73	Trichloroethylene	79016	0.05	-	-	13	-	0.3	0.7
74	Vinyl Chloride	75014	1.5	-	-	1.7	-	-	0.18
75	Zinc	7440666	-	0.50	0.3	-	47	1,000	1,000
^a	This criterion refers to the inorganic form of arsenic only.								
^b	This criterion is expressed as the fish tissue concentration of methylmercury (mg methylmercury/kg fish). See <i>Water Quality Criterion for the Protection of Human Health: Methylmercury</i> (EPA-823-R-01-001, January 3, 2001) for how this value is calculated using the criterion equation in EPA's 2000 Human Health Methodology rearranged to solve for a protective concentration in fish tissue rather than in water.								
^c	This criterion applies to total PCBs (e.g., the sum of all congener or isomer or homolog or Aroclor analyses).								

	A		B					C	
	Chemical	CAS Number	Cancer Slope Factor, CSF (per mg/kg·d) (B1)	Relative Source Contribution, RSC (-) (B2)	Reference Dose, RfD (mg/kg·d) (B3)	Bio-accumulation Factor (L/kg tissue) (B4)	Bio-concentration Factor (L/kg tissue) (B5)	Water & Organisms (µg/L) (C1)	Organisms Only (µg/L) (C2)
*	These criteria were promulgated for Washington in the National Toxics Rule at § 131.36, and are moved into § 131.45 to have one comprehensive human health criteria rule for Washington.								
**	Bis(2-Chloro-1-Methylethyl) Ether was previously listed as Bis(2-Chloroisopropyl) Ether.								

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